DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3101. Misbranding of amphetamine hydrochloride tablets. U. S. v. David Avila (West Side Drug Store). Plea of guilty. Fine of $250, plus costs. (F. D. C. No. 28132. Sample No. 49091–K.)

INFORMATION FILED: March 23, 1950, District of New Mexico, against David Avila, trading as the West Side Drug Store, Albuquerque, N. Mex.

INTERSTATE SHIPMENT: On or about August 9, 1949, from the State of Alabama into the State of New Mexico.

ALLEGED VIOLATION: On or about August 29, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of tablets of the drug to be removed from the bottle in which they had been shipped, to be repacked into a box, and to be sold without a prescription, which acts of the defendant resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502(b)(1), the repackaged tablets bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged tablets bore no label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug, namely, "amphetamine hydrochloride"; Section 502 (f) (1), the repackaged tablets bore no label containing adequate directions for use; and, Section 502 (f) (2), the repackaged tablets bore no labeling containing warnings against use in those pathological conditions, and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 18, 1950. A plea of guilty having been entered, the court imposed a fine of $250, plus costs.

3102. Misbranding of Desoxyn Hydrochloride Tablets. U. S. v. James V. Thompson (Thompson's Drug Store). Plea of guilty. Fine of $300 and costs. (F. D. C. No. 26743. Sample Nos. 37288–K, 37291–K.)

INFORMATION FILED: November 17, 1949, Western District of Washington, against James V. Thompson, trading as Thompson's Drug Store, at Lynden, Wash.

INTERSTATE SHIPMENT: Between the approximate dates of May 28 and August 5, 1948, from North Chicago, Ill.

PRODUCT: The product had been made for use exclusively by or on the prescription of a physician, and the label bore the statement "Caution: To be dispensed only by or on the prescription of a physician." As a result, the product was not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

LABEL, WHEN SHIPPED: "Tablets Desoxyn Hydrochloride 2.5 mg."

ALLEGED VIOLATION: On or about September 10, 1948, while a number of tablets of the article were being held for sale after shipment in interstate commerce, the defendant caused them to be sold and disposed of to a purchaser in the original bottle in which the article had been shipped in interstate commerce, without a physician's prescription. The sale of the article by the defendant caused the exemption to expire and resulted in the misbranding of the article

*See also No. 3119 (veterinary preparations).

in violation of Section 502 (f) (1), since the bottle bore no labeling containing directions for use.

On or about September 30, 1948, the defendant caused a number of tablets to be removed from the bottle in which the tablets had been shipped in interstate commerce, to be repacked into a box, and to be sold without a prescription. The acts of the defendant resulted in the article being misbranded in violation of Section 502 (a), in that the statement "Desoxyn 2 gr.," displayed upon the box into which the tablets had been repacked, was false and misleading since each tablet of the article contained less than 2 grains of Desoxyn; Section 502 (b) (1), the box of tablets bore no label containing a statement of the quantity of the contents; Section 502 (f) (1), the box of tablets bore no labeling containing directions for use; and, Section 502 (f) (2), the box of tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 4, 1950. A plea of quality having been entered, the court imposed a fine of $300, plus costs.

3103. Misbranding of Sedco. U. S. v. 282 Bottles * * *. (F. D. C. No. 28710. Sample No. 47648–K.)

LIBEL FILED: February 7, 1950, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about September 20, 1949, by the Hance Bros. & White Co., from Philadelphia, Pa.

PRODUCT: 282 1-pint bottles of *Sedco* at Norfolk, Va.

LABEL, IN PART: (Bottle) "One Pint Sedco Alcohol 5% Each Fluid Ounce Contains Sod. Pentabarbital ½ gr. May be Habit Forming Phenobarbital ½ gr. May be Habit Forming Ephedrine Sulphate 1 gr. tr Euphorbia 120 m Menthol 2/25 gr. Syr. Squill Compound 21 m Syr. Wild Lettuce 120 m Tr Cocillana 40 m."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the label statement "Dose: As directed by the physician" failed to reveal the quantity of the dose and the frequency of administration.

Further misbranding, Section 502 (d), the article was a drug for use by man and contained derivatives of barbituric acid, namely, sodium pentobarbital and phenobarbital, which derivatives had been by the Federal Security Administrator, after investigation, found to be, and by regulations designated as, habit forming; and its label failed to bear the names, and quantities or proportions of all such substances and derivatives and the statement "Warning—May be habit forming" immediately following (without intervening written, printed, or graphic matter) the name by which the drug was titled in the part or panel of the label presented or displayed under customary conditions of purchase. The statement "Alcohol 5%" intervened between the name of the drug and the names of the habit-forming ingredients, and the prescribed statement was not in the form required by the law and regulations.

DISPOSITION: March 9, 1950. Coastal Pharmaceutical Co., Inc., Norfolk, Va., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.